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Dated: _September 29, 2008__

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(Burton A. Amernick)

Docket No.: 21547-00298-US1 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Andrew Dawood

Application No.: 10/506,632

Filed: September 7, 2004

For: A FIXTURE FOR ORTHODONTIC

ANCHORAGE AND OSSEO DISTRACTION OF THE ALVEOLAR PROCESS, AND FOR THE STABILIZATION OF TEMPORARY

PROSTHESES

Confirmation No.: 3407

Art Unit: 3732

Examiner: M. N. Bumgarner

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Customer Service Window U.S. Patent and Trademark Office Randolph Building 401 Dulany Street Alexandria, Virginia 22314

Dear Sir:

Applicant hereby claims priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

Country	Application No.	Date
United Kingdom	02 05299.1	March 6, 2002

In support of this claim, a certified copy of the said original foreign application is filed herewith.

Application No.: 10/506,632 Docket No.: 21547-00298-US1

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21547-00298-US1 from which the undersigned is authorized to draw.

Dated: September 29, 2008

Respectfully submitted,

Burton A. Amernick

Registration No.: 24,852

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undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of mptroller-General, hereby certify that annexed hereto is a true copy of the documents inally filed in connection with patent application GB0205299.1 filed on 6 March 2002.

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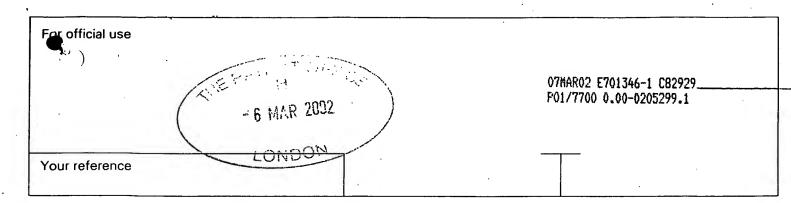
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1 Please give the title A FIXTURE FOR OSSEDDISTRACTION of the invention

OF THE ALVEOLAK PROCESS

Applicant's details 06 MAR 2002

0205299.1

First or only applicant

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2b If you are applying as an individual or one of a partnership please give in full:

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A Fixture for Osseodistraction of the Alveolar Process

Dental implants are fixtures, which may be inserted into the jawbones in order to support dental prostheses. For, many reasons, there are often situations in which there is inadequate bone available in which to place fixtures.

In these situations, various techniques exist which may be used to augment the available bone bulk.

Osseo-distraction (distraction Osseo-genesis) is a surgical process by which the available bone bulk may be increased. This process may be used where there is a local deficiency in jawbone height, prior to the provision of implant-stabilised prostheses. Surgery involves sectioning a segment of the jaw, which must be pedicled on the surrounding soft tissue.

Subsequently, soft tissues are allowed to heal and the bone callus to develop. However after a few days latency, the bony "transport " segment is distracted, thus stretching the healing callus. Distraction proceeds incrementally, and substantial volumes of new bone may be laid down between the transport segment and the bony jaw base.

Varied fixtures and mechanisms have been developed to facilitate this process.

This invention relates to a fixture which when inserted into the transport segment will facilitate the distraction process in conjunction with attachments to adjacent teeth or fixtures. A specific embodiment of this invention will now be described with reference to figures 1 and 2.

With reference to Figure 1, there is provided a fixture, which may be made of machined titanium or a machined titanium alloy. The fixture may broadly be categorised as containing three segments.

An alignment section (1) is provided having a smooth surface, and relatively small diameter. A bone interfacing (2) retentive section is provided having a deep-set steeply pitched thread on a slightly tapered base (taper exaggerated in diagram).

A non-axially symmetrical collar (3) facilitates insertion of the device by means of a matched insertion tool, which fits over the intra oral part (4) of the fixture, rather like a socket spanner. This part is polished to allow a gingival cuff to develop around the fixture.

The intra oral part of the fixture (4) comprises a narrow extension provided with a machine screw threading.

Surgery proceeds as follows, with reference to figures 1& 2:

Following elevation of a surgical flap, a horizontal osteotomy is performed (A) at the base of the future transport segment (B).

Before the transport section is mobilized by the vertical osteotomies (C), a site is prepared for the distraction fixture or fixtures; having marked the site with a round burr a 1.2mm twist drill is inserted beyond the depth of the horizontal osteotomy, such that it the site is prepare in bone of good bulk and quality.

A second twist drill is then inserted into the prepared site, having a slightly greater diameter, e.g. 1.6mm, to the depth of the horizontal osteotomy

If visibility and access to the site is unimpaired the surgeon may then continue to carry out the vertical osteotomy, thus freeing the transport section. However generally the osteotomy is only carried out to an extent, which will allow the transport segment to be easily mobilized once the fixtures have been placed.

The distraction fixture is then placed by means of an insertion tool that properly mates with the non-axially symmetrical collar such that the alignment section (1) travels through the narrowly prepared depth of the site. The threaded section (2) is tapped through the prepared site such that it engages the transport segment.

The threaded intra oral section (4) then protrudes into the mouth such that it is aligned with adjacent teeth or fixtures, and the main bulk of the bone is in the intended trajectory.

Following latency, or healing period of four-seven days distraction may begin. For distraction to take place there may be provided either a temporary prosthesis which serves to provisionally replace the missing teeth, or a simple appliance, (D), which may take the form of a cast bar, resin reinforced structure, or orthodontic appliance anchored to adjacent teeth of fixtures.

A prosthesis or appliance may be provided with a portion through which the threaded part of the distraction implant protrudes. Distraction may then be accomplished by tightening a nut (5) onto the machined threaded section so as to pull it through the channel, thus distracting the bony segments. As the portion of the threaded section protrudes past the nut, it may be sectioned so as to avoid interference within the mouth. Once distraction has taken place to the planned extent the arrangement is left in place for a subsequent period of six-eight weeks until the transport segment has stabilised, and bone has formed in the space between the segment and the bony base.

An orthodontic appliance may be fitted with a novel component which is designed to fit onto the arch wire of a fixed appliance, and mate with the head of the distraction fixture, thus allowing the distraction process to be controlled accurately in three dimensions.

Where distraction must take place over a substantial span, there may also be provided extension pieces (6) having an internally threaded tube at one end, which may be rotated over the threaded head of the fixture, and a nut at the other end to permit the piece to be rotated into place, and allow distraction to take place

Claims

- 1. A fixture having external threading, comprising, 1/a threaded Part for insertion into a prepared site in the jaw bone, and 2/a threaded part, to which pressure may be applied by means of an internally threaded element e.g. a nut, when used in conjunction with an appliance supported by teeth or adjacent static fixtures.
- 2. A one piece implant for osseodistraction, having a threaded part for insertion into bone, with the characteristics of a dental implant for insertion into bone, at one end, and the characteristics of a machine screw at the other end, which is intended to protrude into the mouth.
- 3. A fixture as described in previous claims, having two externally threaded parts, one which is inserted into a prepared site into the jaw bone, the other which protrudes into the oral cavity so that it may be acted upon by an internally threaded component eg a nut.
- 4. A fixture as described in the previous claim having a smooth, parallel sided alignment section at its' apex, intended to guide the transport segment of bone as it is distracted and prevent inappropriate movement.
- 5. A fixture as described in previous claims, which is provided with a polished section, intended to act as a collar to which the gingival cuff will approximate, said collar having a non round cross-section to allow insertion of the fixture with an appropriate shaped socketed tool.
- 6. A fixture as described in previous claims intended for connection to prostheses, orthodontic appliances, or adjacent teeth or dental implants.
- 7. A fixture as described in previous claims having a slightly tapered part, having deeply biting threads, on that part intended for insertion into the jaw, and a metric machine thread on that part intended to protrude through the gingiva.
- 8. A fixture intended for osseodistraction in the jaw, substantially as described in this description and the accompanying figures.

